arabicum, guar gummi, xanthan gummi, polyethylene oxide, polypropylene oxide, and copolymers of ethylene oxide and propylene oxide.

REMARKS

Claims 1-30 are presented. Claims 1, 4-5, 9, 11, 14-16, 19, 21, 23-25, 27-29 have been amended. Claim 30 has been added and no claims have been canceled.

The claims have been amended to remove multiple dependencies and to effect minor editorial amendments.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version with markings to show changes made.**" Entrance of the foregoing amendments and an early and favorable Action is respectfully requested.

Respectfully submitted,

Date: 6/21/01

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the claims:

Please amend claims 1, 4-5, 9, 11, 14-16, 19, 21, 23-25, 27-29 as follows:

1. (Amended) A controlled release formulation containing galantamine as the active ingredient, [characterized in that it comprises] comprising particles comprising galantamine or a pharmaceutically acceptable acid addition salt thereof, and a water soluble pharmaceutically acceptable excipient [and optionally other pharmaceutically acceptable excipients], said particles being coated by a release rate controlling membrane coating.

4. (Amended) A formulation according to claim 3 wherein the water soluble film forming polymer is a polymer that has an apparent viscosity of 1 to 100 mPa.s [when dissolved in a 2% aqueous solution at 20°C solution].

5. (Amended) A formulation according to claim 4 wherein the water soluble polymer is selected from [the group comprising]
   [-] (a) alkylcelluloses [such as methylcellulose],
   [-] (b) hydroxyalkylcelluloses [such as hydroxymethylcellulose, hydroxyethylcellulose,
   - hydroxypropylcellulose and hydroxybutylcellulose],
   [-] (c) hydroxyalkyl alkylcelluloses [such as hydroxyethyl methylcellulose and hydroxypropyl methylcellulose],
   [-] (d) carboxyalkylcelluloses [such as carboxymethylcellulose],
   [-] (e) alkali metal salts of carboxyalkylcelluloses [such as sodium carboxymethylcellulose],

[-] (f) carboxyalkylalkylcelluloses [such as carboxymethylethylcellulose],
[-] (g) carboxyalkylcellulose esters,
[-] (h) starches,
[-] (i) pectines [such as sodium carboxymethylamylopectine],
[-] (j) chitine derivatives [such as chitosan],
[-] (k) polysaccharides [such as alginic acid, alkali metal and ammonium salts thereof, carrageenans, galactomannans, traganth, agar-agar, gummi arabicum, guar gummi and xanthan gummi],
[-] (l) polyacrylic acids and the salts thereof,
[-] (m) polymethacrylic acids and the salts thereof, methacrylate copolymers,
[-] (n) polyvinylalcohol,
[-] (o) polyvinylpyrrolidone, copolymers of polyvinylpyrrolidone with vinyl acetate, or
[-] (p) polyalkylene oxides [such as polyethylene oxide and polypropylene oxide and copolymers of ethylene oxide and propylene oxide].

9. (Amended) A formulation according to claim 8 wherein the inert spheres are 16-60 mesh [(1,180-250 • m)] sugar spheres [(NF XVII, page 1989)].

11. (Amended) A formulation according to claim 10 wherein the water insoluble polymer is ethylcellulose and the plasticizer is selected from the group [comprising] consisting of dibutyl sebacate, diethyl phthalate and triethyl citrate.

14. (Amended) A formulation according to [any one of] claim[s] 1 [to 13] further comprising a topcoat comprising galantamine and water-soluble polymer.

15. (Amended) A formulation according to claim 14 capable of releasing [in USP buffer pH 6.8 at 37°C in an Apparatus 2 (USP 23, <711> Dissolution, pp 1791-1793, paddle, 50 rpm)] from 20 to 40 % of the total amount of galantamine.HBr in 1 hour, and more than 80 % of the total amount of galantamine.HBr in 10 hours.

16. (Amended) A dosage form comprising a therapeutically effective amount of the controlled release formulation of [any of] claim[s] 1 [to 15].

19. (Amended) A dosage form according to claim 18 wherein said immediate release form comprises particles [as described in claim 1 lacking the release rate controlling membrane] comprising galantamine or a pharmaceutically acceptable acid addition salt thereof, and a water soluble pharmaceutically acceptable excipient.

21. (Amended) A dosage form according to claim 18 wherein said immediate release form comprises [a] said controlled release formulation [of claim 14] , and a topcoat comprising galantamine and water-soluble polymer.

23. ~~(Amended) A pharmaceutical package~~ [suitable for commercial sale] comprising a container, a formulation of galantamine as claimed in claim 1, and [associated with said package] written matter specifying how said formulation should be administered.

24. (Amended) A pharmaceutical package as claimed in claim 23 adapted for [titrating] treating a patient who is [']acetylcholine esterase inhibitor[']-naïve, [characterized in that said package comprises] comprising 21-35 daily sequential dosage units of
(a) a first group of 7 to 14 dosage units comprising from 5 to 10 mg galantamine,
(b) a second group of 7 to 14 dosage units comprising from 10 to 20 mg galantamine,
(c) a third group of 7 to 14 dosage units comprising from 15 to 30 mg galantamine, and
(d) optionally a fourth group of 7 dosage units comprising from 20 to 40 mg galantamine.

25. (Amended) A pharmaceutical package as claimed in claim 23 adapted for treating a patient who is [']acetylcholine esterase inhibitor[']-tolerant, [characterized in that said package comprises] comprising daily dosage units comprising from 15 to 30 mg galantamine.

27. (Amended) A method of treating Alzheimer's dementia and related dementias in a human while substantially reducing [(avoiding)] the concomitant liability of adverse effects associated with acetyl cholinesterase inhibitors, comprising administering to a human in need of such treatment, a therapeutically effective amount of galantamine in a controlled release formulation as claimed in claim 1, said amount being sufficient to alleviate said Alzheimer's dementia and related dementias, but insufficient to cause said adverse effects.

28. (Amended) A method according to claim 27 wherein the related dementia [belongs to] is selected from the group consisting of vascular dementia, Lewy body disease, autism, mental retardation, bipolar disorder psychiatric conditions, disruptive behaviour, attention deficiet, hyperactivity disorder, substance abuse, extreme aggression, especially conduct disorder, nicotine cessation and withdrawal.

29. (Amended) A method according to claim 27 wherein the adverse effects [belong to] are selected from the group [comprising] consisting of nausea, vomiting, sweating, restlessness, and insomnia.

Please add claim 30 as follows:

30. (New) A formulation according to claim 5 wherein the water soluble polymer is selected from the group consisting of methylcellulose, hydroxymethylcellulose, hydroxyethylcellulose, hydroxypropylcellulose, hydroxybutylcellulose, hydroxyethyl methylcellulose, hydroxypropyl methylcellulose, carboxymethylcellulose, sodium carboxymethylcellulose, carboxymethylethylcellulose, sodium carboxymethylamylopectine, chitosan, alginic acid, alkali metal and ammonium salts thereof, carrageenans, galactomannans, traganth, agar-agar, gummi arabicum, guar gummi, xanthan gummi, polyethylene oxide, polypropylene oxide, and copolymers of ethylene oxide and propylene oxide.